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Quality improvement in acute stroke

The New York State Stroke Center Designation Project

T.I. Gropen, MD; P.J. Gagliano, MD; C.A. Blake, BA; R.L. Sacco, MD; T. Kwiatkowski, MD;
N.J. Richmond, MD; D. Leifer, MD; R. Libman, MD; S. Azhar, MD; and M.B. Daley, RN,
for the NYSDOH Stroke Center Designation Project Workgroup

Abstract—Background: Many hospitals lack the infrastructure required to treat patients with acute stroke. The Brain Attack Coalition (BAC) published guidelines for the establishment of primary stroke centers. **Objective:** To determine if stroke center designation and selective triage of acute stroke patients improve quality of care. **Methods:** Baseline chart abstraction was performed on all stroke patients admitted to 32 hospitals serving Brooklyn and Queens, NY, from March to May 2002. Hospitals were invited to meet BAC guideline-based criteria. Adherence was verified by on-site visits. After designation, acute stroke patients were selectively triaged. Remeasurement data were collected from August to October 2003. **Results:** The authors abstracted 1,598 charts at baseline and 1,442 charts at remeasurement. From baseline to remeasurement, median times decreased for door to physician contact (25 vs 15 minutes, $p = 0.001$), CT performance for potential tissue plasminogen activator (t-PA) candidates (68 vs 32 minutes, $p < 0.001$), and t-PA administration (109 vs 98 minutes ($p = \text{NS}$)). IV t-PA utilization increased from 2.4 to 5.2% ($p < 0.005$), select t-PA protocol violations decreased from 11.1 to 7.9% ($p = \text{NS}$), and the stroke unit admission rate increased from 16 to 39% ($p < 0.001$). In stroke centers ($n = 14$) vs nondesignated hospitals ($n = 18$), there were shorter median times from door to physician contact (10 vs 25 minutes, $p < 0.001$), CT performance for potential t-PA candidates (31 vs 40 minutes, $p = \text{NS}$), and t-PA administration (95 vs 115 minutes, $p < 0.05$). Stroke centers, compared with nondesignated centers, admitted acute stroke patients to stroke units more often (55.9 vs 10.9%, $p < 0.001$). **Conclusions:** Stroke center designation and selective triage of acute stroke patients improved the quality of care, including access to timely thrombolytic therapy and stroke units.

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Inadequate integration of the various facilities, agencies, and professionals that provide stroke care is one of the obstacles to delivery of effective new stroke therapies.¹ Stroke center development is one approach to improving the stroke care medical infrastructure. Studies suggest that several key elements of stroke centers, including acute stroke teams, stroke units, written care protocols, and an integrated emergency response system, improve the quality of stroke care and outcomes. A consensus-based approach to the establishment of primary stroke centers was developed by the Brain Attack Coalition (BAC) and published in 2000.² However, no study has prospectively evaluated the benefits of stroke center designation using BAC criteria.

The New York State Department of Health Stroke Center Designation Project was a collaboration between the New York State Department of Health (NYSDOH), the Fire Department of New York Emergency Medical Service (FDNY EMS), the American Heart Association (AHA), and IPRO (the New York State Quality Improvement Organization). The primary goal was to determine whether an integrated system linking early recognition and transport of acute stroke patients to designated stroke centers would improve quality of care for patients with stroke within two urban New York City boroughs, Brooklyn and Queens. A key study objective was to prospectively validate BAC primary stroke center guidelines.

Additional material related to this article can be found on the *Neurology* Web site. Go to www.neurology.org and scroll down the Table of Contents for the July 11 issue to find the title link for this article.

Methods. The NYSDOH appointed a steering committee (see appendix E-1 on the *Neurology* Web site; go to www.neurology.org) in the spring of 2002. It consisted of neurologists, Emergency Department (ED) physicians, and representatives from the NYSDOH, FDNY EMS, and IPRO and was responsible for the study

From the Departments of Neurology (T.I.G.), Long Island College Hospital and State University of New York–Health Science Center at Brooklyn, IPRO (P.J.G., M.B.D.), Lake Success, Healthcare Quality Initiatives (C.A.B.), New York State Department of Health, New York, Departments of Neurology and Epidemiology (R.L.S.), Columbia University Medical Center, New York, Department of Emergency Medicine (T.K.) and Division of Cerebrovascular Disease (R.L.), Long Island Jewish Medical Center, New Hyde Park, Department of Neurology (D.L.), North Shore University Hospital, Manhasset, Department of Neurology (D.L.), Weill Medical College of Cornell University–New York Presbyterian Hospital, New York, and Stroke Center (S.A.), Lutheran Medical Center, Brooklyn, NY; and New York City Fire Department and Louisville Metro EMS (N.J.R.), Louisville, KY.

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Address correspondence and reprint requests to Dr. T.I. Gropen, Neurology Department, Long Island College Hospital, 339 Hicks St., Brooklyn, NY 11201; e-mail: tgropen@chnpnet.org

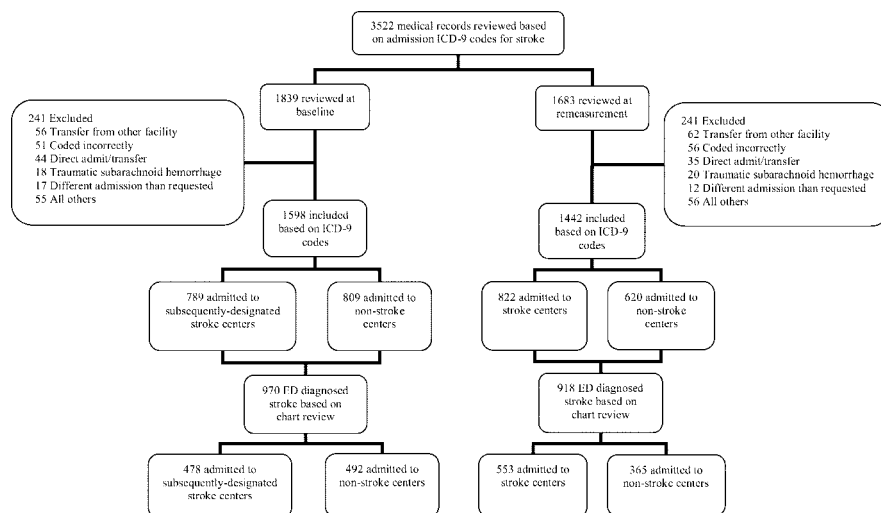


Figure. Study flow diagram of participants. ICD-9 = International Classification of Diseases (9th ed.).

design, criteria for stroke center designation, quality indicators, and adjudication of protocol violations and complications.

Sampling and data collection. With use of the NYSDOH's Statewide Planning and Research Cooperative System (SPARCS) data, all stroke cases from 32 hospitals serving Kings and Queens Counties were identified during the baseline and remeasurement time periods of March 1, 2002 through May 31, 2002 and August 1, 2003 through October 31, 2003. Hospital records were requested based on the admitting diagnosis, using the following International Classification of Diseases (9th ed.; ICD-9) codes: ischemic stroke (433.x1, 434.x1, 436) and hemorrhagic stroke (430,431,432.9). In total, 1,839 and 1,683 medical records were available for review at baseline and remeasurement.

A standardized abstraction instrument was developed, and then used by trained nurses at IPRO. To ensure accurate abstraction, nurses achieved results ranging from 97 to 100% on a gold standard comparison on two cases at baseline and remeasurement. At baseline, internal quality control was performed on all cases. At remeasurement, (interrater) reliability testing on 15 randomly selected charts resulted in >90% agreement. Of the 1,839 baseline medical records, 241 (13.1%) were excluded, leaving 1,598 for analysis. Of the 1,683 remeasurement medical records, 241 (14.3%) were excluded, leaving 1,442 (figure).

Stroke center designation process. In July 2002, the NYSDOH invited 32 hospitals serving the boroughs of Queens and Brooklyn to participate, including a medical school-associated academic medical center, affiliated teaching hospitals, and community hospitals. Hospitals completed a stroke care survey, based on BAC recommendations for the establishment of primary stroke centers.² To be considered for pilot designation, hospitals were required to answer affirmatively all of the required survey questions. Of the 32 hospitals, 29 completed the survey, and 5 met all of the required criteria. The 24 remaining hospitals were sent a second survey and were then allowed 30 days to become compliant with all required criteria. In total, 20 hospitals met all required criteria.

Onsite visits for these 20 hospitals were performed from October 8, 2002, through November 26, 2002, to validate the survey responses. Visits were conducted by a physician and nurse from IPRO and included review of written documentation and tracking systems, visits to the ED, CT scan suite, and stroke unit, and staff interviews.

A consensus process in the workgroup was used to develop BAC Core Elements (see appendix E-2). The BAC core criteria were used to validate survey responses and determine stroke center designation. Stroke center designation was determined by consensus with workgroup members blinded to hospital identity. On May 5, 2003, 14 hospitals obtained pilot designated stroke center status. Five additional hospitals met BAC core criteria and were granted pilot designated stroke center status on September 7, 2003. For the purposes of this analysis, only the original 14 hospitals were considered stroke centers, whereas the remaining 18 hospitals (including the 5 late-designated hospitals) were considered nondesignated centers.

Several measures were undertaken to maximize adherence of stroke centers to BAC core criteria. These included a "kick-off" educational meeting and subsequent regional AHA-sponsored continuing medical education (CME) activities, distribution of written care protocols, development and distribution of a Stroke Code Flow Record to minimize tissue plasminogen activator (t-PA) protocol violations and aid in data abstraction (see appendix E-3), and use of an online interactive community server to share information and address common questions. Interim data from stroke centers were collected and compared with baseline data from these hospitals. The data were used to provide timely feedback and facilitate adherence to core BAC guidelines.

EMS training and selective triage of acute stroke patients. EMS providers were instructed in the use of a prehospital stroke scale. The scale included the previously validated Cincinnati Prehospital Stroke Scale,³ which assesses facial weakness, arm weakness, and speech. In addition, time elapsed from onset of symptoms was estimated based on when the patient was last known to be in his/her usual state of health. Starting May 5, 2003, a change in protocol in the EMS triage of acute stroke patients was instituted in Brooklyn and Queens. Patients with any abnormal finding on the stroke scale and a time elapsed from onset of symptoms of ≤2 hours were transported to the closest available designated stroke center, unless it was >20 minutes away or the patient was in extremis.

Quality indicator development. Quality indicators were developed via a consensus process within the stroke workgroup (see appendix E-4). The population of patients potentially eligible for t-PA was defined as all patients with a presumptive diagnosis of stroke (diagnosis in ED prior to full ED evaluation) with symptom onset ≤3 hours of arrival to the ED. The ED diagnosis of stroke was based on the clinician's diagnosis after ED evaluation rather than ICD-9 codes. ED diagnosis of stroke yielded positive predictive values of 78 and 98% for discharge diagnoses of ischemic and hemorrhagic stroke. Discharge diagnosis was based on the clinician's impression after inpatient evaluation as reflected in the discharge summary, and in progress and consult notes.

Adjudication of protocol violations and complications. All cases of suspected protocol violations and post-t-PA complications were adjudicated by members of the workgroup. Workgroup members reviewed the hospital records and were blinded with respect to patient and hospital identity and designation status. Records were reviewed together regardless of measurement period. A consensus between two independent reviewers was required for classification.

Analysis. Stroke quality indicators were assessed at baseline and during the remeasurement phase. Data were analyzed in the aggregate by measurement period and by stroke center designation status within and between measurement periods. Only the original 14 pilot centers comprised the designated group as they functioned as stroke centers for the entirety of the project. The χ^2 significance testing was performed for proportions with significant differences defined at the 0.05 level ($p < 0.05$). For categories with $n < 5$, we applied Fisher exact test. For the time variables, me-

Table 1 Demographics and selective triage of acute stroke patients

Characteristic	Baseline, n = 1,598	Remeasurement, n = 1,442	p
Age, mean; y	71.8	70.4	0.01
Female, no. (%)	874 (54.8)	839 (58.5)	0.04
Ethnicity, no. (%)			
White	702 (44.0)	614 (42.6)	0.44
African American	514 (32.2)	433 (30.0)	0.20
Other ethnicity	258 (16.2)	302 (20.9)	0.001
Unknown	123 (7.7)	93 (6.5)	0.18
Hispanic	167 (10.5)	175 (12.2)	0.13
Mode of arrival, no. (%)			
Arrived by FDNY	665 (41.6)	605 (42.0)	0.85
Arrived by other ambulance	378 (23.7)	350 (24.3)	0.69
Arrived by nonambulance	555 (34.7)	487 (33.8)	0.58
ED-diagnosed stroke, no. (%)	970 (60.7)	918 (63.7)	0.09
ED-diagnosed stroke admitted to stroke center,* no. (%)	478 (49.3)	553 (60.2)	<0.001
ED-presumed stroke arriving within 3 h, no. (%)	239 (15.9)	261 (19.9)	0.006
ED-presumed stroke arriving within 3 h admitted to stroke center,* no. (%)	126 (52.7)	199 (76.2)	<0.001
Intracerebral hemorrhage, no. (% of ED-diagnosed stroke)	207 (21.3)	190 (20.7)	0.73
Intracerebral hemorrhage admitted to stroke center,* no. (%)	120 (58.0)	136 (71.6)	<0.005

*Refers to subsequently designated stroke centers at baseline and stroke centers at remeasurement.

FDNY = Fire Department of New York; ED = Emergency Department.

dian values were reported, and the differences were tested employing the Wilcoxon nonparametric test. To assess for misclassification errors related to assignment of the five late-designated hospitals to the nondesignated group, an additional secondary analysis was undertaken with these five centers removed from analysis.

Results. *Selective triage of acute stroke patients.* As shown in table 1, at baseline, 49.3% of ED-diagnosed stroke patients were admitted to a hospital subsequently designated vs 60.2% of cases admitted to stroke centers at remeasurement ($p < 0.001$). At baseline, 15.9% of presumed stroke patients presented to the ED within 3 hours from symptom onset vs 19.9% during remeasurement ($p = 0.006$). At baseline, 52.7% of these potential t-PA candidates were admitted to hospitals

subsequently designated vs 76.2% admitted to stroke centers at remeasurement ($p < 0.001$). At baseline, 58.0% of hemorrhages were admitted to hospitals subsequently designated vs 71.6% admitted to stroke centers at remeasurement ($p < 0.005$).

Performance at baseline vs remeasurement. As shown in table 2, from baseline to remeasurement, median times decreased for door to physician contact (25 vs 15 minutes, $p = 0.001$) and CT performance for potential t-PA candidates (68 vs 32 minutes, $p < 0.001$). The proportion of ischemic stroke patients who received t-PA increased from 2.4% (18/763) at baseline to 5.2% (38/728) at remeasurement ($p = 0.004$). Thrombolysis of eligible patients increased from 21.8% (17/78) at baseline to 38.7% (36/93) at remeasurement ($p = 0.02$). There were no significant dif-

Table 2 Performance at baseline vs remeasurement, aggregate data

Time intervals, (min)	Baseline			Remeasurement			p
	n	Median	Range	n	Median	Range	
Door to MD assessment	398	25.0	(0–348)	424	15.0	(0–1,460)	0.001
Door to CT performed, potential t-PA candidates	168	67.5	(2–519)	197	32.0	(3–775)	<0.001
Door to t-PA administration	18	108.5	(45–275)	38	98.0	(40–165)	0.12

Rates	Baseline		Remeasurement		p
	Den	%	Den	%	
Eligible patients who received t-PA	78	21.8	93	38.7	0.02
Infarct patients who received t-PA	763	2.4	728	5.2	0.004
Select t-PA protocol violations	18	11.1	38	7.9	0.69
Post-t-PA hemorrhagic complications	18	27.8	38	18.4	0.43
ED-diagnosed stroke cases admitted to stroke unit	622	15.6	642	38.6	<0.001
Peristroke complications	712	22.9	710	26.5	0.12
Discharge home	1,035	36.3	967	36.7	0.86

t-PA = tissue plasminogen activator; ED = emergency department; Den = denominator. For definitions of quality indicators, see appendix E-4.

Table 3 Performance of designated vs nondesignated centers by measurement period

	Baseline							Remeasurement						
	Designated*			Nondesignated			<i>p</i>	Designated*			Non-designated			<i>p</i>
	<i>n</i>	Median	Range	<i>n</i>	Median	Range		<i>n</i>	Median	Range	<i>n</i>	Median	Range	
Time intervals, min														
Door to MD assessment	193	25.0	(0–331)	205	21.0	(0–348)	0.94	278	10.0	(0–1,460)	146	25.0	(0–371)	<0.001
Door to CT performed, potential t-PA candidates	80	49.0	(2–266)	88	92.0	(11–519)	0.02	156	30.5	(3–775)	41	40.0	(5–653)	0.25
Door to t-PA administration	12	115.0	(67–180)	6	105.5	(45–275)	0.85	32	95.0	(40–165)	6	115.0	(97–140)	0.047

Rates	Baseline					Remeasurement				
	Designated*		Nondesignated		<i>p</i>	Designated*		Nondesignated		<i>p</i>
	Den	%	Den	%		Den	%	Den	%	
Eligible patients who received t-PA	36	30.6	42	14.3	0.08	71	43.7	22	22.7	0.08
Infarct patients who received t-PA	358	3.4	405	1.5	0.09	417	7.7	311	1.9	0.001
Select t-PA protocol violations	12	8.3	6	16.7	1.0	32	6.3	6	16.7	0.41
Post-t-PA hemorrhagic complications	12	25.0	6	33.3	1.0	32	21.9	6	0.0	0.60
ED-diagnosed stroke cases admitted to stroke unit	318	30.2	304	0.3	<0.001	395	55.9	247	10.9	<0.001
Peristroke complications	405	21.5	307	24.8	0.30	452	25.7	258	27.9	0.52
Discharge home	574	37.6	461	34.7	0.33	615	36.7	352	36.6	0.98

*Refers to subsequently designated stroke centers at baseline and stroke centers at remeasurement.

Den = denominator; t-PA = tissue plasminogen activator; ED = emergency department. For definitions of quality indicators, see appendix E-4.

ferences in the number of protocol violations, the percentage of patients with one or more post-t-PA hemorrhagic complications, or the incidence of symptomatic hemorrhagic infarction within or greater than 36 hours of treatment with t-PA. The percentage of acute stroke patients admitted to a stroke unit increased from 15.6% at baseline to 38.6% at remeasurement ($p < 0.001$).

Performance of designated vs nondesignated centers. As shown in table 3, at remeasurement, in stroke centers ($n = 14$) vs nondesignated hospitals ($n = 18$), there were shorter median times from door to physician contact (10 vs 25 minutes, $p < 0.001$) and t-PA administration (95 vs 115 minutes, $p < 0.05$). Compared with nondesignated centers, designated centers treated more ischemic stroke patients with t-PA (7.7 vs 1.9%, $p = 0.001$) and tended to treat more eligible patients with t-PA (43.7 vs 22.7%, $p = 0.08$). Stroke centers, compared with nondesignated centers, admitted acute stroke patients to stroke units more often (55.9 vs 10.9%, $p < 0.001$).

In contrast, during the baseline period, the only significant differences between hospitals subsequently designated as stroke centers and hospitals that remained nondesignated were in time from door to CT performance for potential t-PA candidates (49 vs 92 minutes, $p = 0.02$) and in the rate of stroke unit admission (30.2 vs 0.3%, $p < 0.001$).

Performance at baseline vs remeasurement by designation status. In stroke centers, at remeasurement compared with baseline, there were shorter median times from door to physician contact (10 vs 25 minutes, $p < 0.001$) and CT performance for potential t-PA candidates (31 vs 49 minutes, $p = 0.003$) and a trend toward shorter median times from door to t-PA administration (95 vs 115 minutes, $p = 0.06$). In stroke centers, at remeasurement compared with baseline, more ischemic stroke patients were treated

with t-PA (7.7 vs 3.4%, $p = 0.01$). In stroke centers, at remeasurement compared with baseline, more stroke patients were admitted to a stroke unit (55.9 vs 30.2%, $p < 0.001$).

In contrast, the only differences in nondesignated hospitals between remeasurement and baseline were in time from door to CT performance for potential t-PA candidates (40 vs 92 minutes, $p = 0.02$) and in the rate of stroke unit admission (10.9 vs 0.3%, $p < 0.001$).

Results with five late-designated hospitals removed from analysis. When the five late-designated hospitals were removed from analysis, the number of t-PA cases in the nondesignated group decreased from six to three, and the difference in door to t-PA administration time between designated and nondesignated centers became nonsignificant. Additionally, in this analysis, t-PA was administered beyond 3 hours of symptom onset more often in nondesignated hospitals compared with stroke centers ($p < 0.05$), but this is based on only three cases in nondesignated hospitals.

Discussion. Our data provide prospective validation of the benefits of the BAC primary stroke center concept and a model of integrated acute stroke care services. We found that stroke center designation and selective triage of acute stroke patients were associated with improved quality of care for patients in Brooklyn and Queens. In part, this was related to more timely assessment, diagnosis, and treatment of stroke patients. Stroke patients received physician evaluation almost twice as rapidly once they reached a hospital, and brain CT was performed twice as rapidly for potential t-PA candidates. Care was streamlined, and appropriate use of t-PA was more

than doubled, without an increase in protocol violations or complications. Finally, stroke patients were more than twice as likely to receive stroke unit care.

Improved care for stroke patients was related in part to the institution of an integrated emergency response system. This required collaboration of the NYSDOH and New York City EMS. The effectiveness of our selective triage is suggested by the fact that more than three times more potential t-PA candidates were evaluated in stroke centers compared with nondesignated hospitals. This is meaningful because stroke centers provided significantly more rapid emergency evaluation, shorter times to t-PA treatment, and greater access to stroke units. The improvement in door to needle time observed in stroke centers may be partly related to more rapid physician evaluation and performance of CT. We suspect that a greater comfort level with thrombolytic therapy on the part of the physicians at designated centers contributed to faster decision making. We found that improvement in most performance measures from baseline to remeasurement occurred in stroke centers rather than nondesignated hospitals, supporting the benefits of stroke center designation based on the BAC criteria.

One recent study has correlated specific BAC elements with increased t-PA use.⁴ This study of selected academic medical centers analyzed individual BAC elements ascertained by survey. This study did not require centers to fulfill BAC criteria, attempt to validate survey results, or selectively triage patients to stroke centers. Another recent study examined the effects of a multilevel educational program partly based on BAC guidelines on six Houston-area hospitals, paramedics, and the community.⁵ Similar to our study, this study showed a shift of stroke patients to participating hospitals (albeit without mandated triage) and an increase in the number of patients presenting within the 3-hour t-PA window. However, in this study there was no validation of hospital compliance with BAC criteria. This might explain the observed increase in door to CT interpretation times and decrease in t-PA use in some of the hospitals and underscores the need for both integration of prehospital and hospital acute stroke services and for validation of compliance with BAC criteria.

Our study focuses on improving delivery of care, rather than demonstrating efficacy of established treatments such as IV thrombolytic therapy⁶ and stroke unit care.⁷ Yet, the literature on the use of t-PA in clinical practice suggests potential for harm⁸⁻¹⁰ as well as benefit.¹¹⁻¹⁵ The occurrence of symptomatic intracerebral hemorrhage has been related to protocol violations in some studies^{10,14} but not others.^{8,15} Our findings extend the Cleveland experience that a structured system emphasizing quality improvement, written care protocols, stroke teams, and CME can result in increased use of t-PA, fewer protocol deviations, and better outcomes.¹¹

At the start of the study, about one-sixth of stroke patients in Brooklyn and Queens had access to stroke unit care, consistent with surveys that have found stroke units in a minority of hospitals.^{16,17} An important finding in our study was the increase in the stroke unit admission rate to almost 40% of stroke patients. This is a conservative estimate of the increase in stroke unit admissions, as we did not include stroke patients admitted to intensive or coronary care units. Stroke unit care has been associated with lower mortality and better functional recovery,⁷ is applicable to the full spectrum of stroke patients, and may have a magnitude of benefit comparable with IV t-PA.^{1,18}

Even during the remeasurement period, only about one-fifth of stroke patients in Brooklyn and Queens presented to the ED within 3 hours. These findings are consistent with literature that the most commonly cited reason for inability to treat with t-PA is presentation to the ED beyond 3 hours.¹⁹ Clearly, more attention needs to be focused on public education, which was not the focus of our study.

Our study has limitations. This was not a randomized trial. Groups differed in demographics, and no risk adjustment was performed. Accordingly, interpretation of outcomes such as complication rates, dispositions, and mortality is difficult. The likelihood that stroke centers treated a more severely ill population is suggested by the disproportionate number of patients with intracerebral hemorrhage treated at stroke centers in our study as well as prior studies associating early stroke presentation with greater stroke severity.^{20,21} Results related to the process of acute stroke care should not be affected by these limitations. A potential limitation relates to the retrospective nature of chart review. We believe that the impact of this limitation is small as we have focused on generally well documented measures of performance. For example, we have focused on the time of CT scan performance rather than the time of CT scan interpretation. Any potential limitation related to inclusion of the five late-designated hospitals is mitigated by the results of our secondary analysis excluding these centers. We may be underestimating the benefits of stroke centers as we used a kick-start approach, with limited time for learning and relatively inexperienced stroke centers, and nondesignated centers benefited from regional educational activities. Finally, our study included a wide range of urban hospitals in an environment with multiple EMS providers. We believe our results are widely generalizable but may not apply to a rural environment. Stroke center designation in our study is similar to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) stroke center certification,²² suggesting that the superior performance of our stroke centers can be generalized to JCAHO-certified stroke centers.

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**Quality improvement in acute stroke: The New York State Stroke Center
Designation Project**

T. I. Gropen, P. J. Gagliano, C. A. Blake, R. L. Sacco, T. Kwiatkowski, N. J. Richmond,
D. Leifer, R. Libman, S. Azhar, M. B. Daley and for the NYSDOH Stroke Center
Designation Project Workgroup

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